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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,662	12/13/2005	Shigeki Hibi	1056-0126PUS1	1432

2292 7590 02/05/2007
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EXAMINER	
RAHMANI, NILOOFAR	
ART UNIT	PAPER NUMBER
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,662	HIBI ET AL.	
	Examiner	Art Unit	
	Niloofar Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, and 20-22 are pending in the instant application. Claims 12-19, and 23-24 are cancelled.

Priority

2. This application is filed on 12/13/2005, which is a 371 of PCT/JP03/13490, file on 10/22/2003, which claims benefit of 60/421,071, filed on 10/25/2002, which claims priority of JAPAN 2002-306695, filed on 10/22/2002.

3. *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-22 are rejected because the term "therapeutic" is vague and unclear. What is the "therapeutic" means? Does it mean "method of treating" or " pharmaceutical composition"? Correction is required.

4. Claims 1-11, and 20-22 are rejected because the term "hydrate" is confusing. What does it mean by them? It is recommended to correct to hydrate thereof.

5. *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 20-22 lack description of the claims i.e. " hydrate". Hydrate is unpredictable because there are different hydrates. There are ½ hydrate, 3 hydrates, or ¾ hydrate, etc. Therefore, the specification lacks description of "hydrate".

6. Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of

experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.
2) The nature of the invention,
3) The state of the prior art,
4) The level of one of ordinary skill,
5) The level of predictability in the art,
6) The amount of direction provided by the inventor,
7) The existence of working examples,
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to a therapeutic method for a disease associated with cortocotropin releasing factor (CRF) or depression, anxiety, mania, panic disorder, phobia, obsessive-compulsive disorder, posttraumatic stress disorder, affective disorder, dysthymia, bipolar disorder, cyclothymic personality or schizophrenia, using a compound of formula (I).

The state of the prior art: " Crticotropin-releasing hormone (CRH) is a key neuroendocrine factor implementing endocrine, immune and behavioral responses to stress. Furthermore the expression of CRH receptors was analyzed for the first time in pituitaries of suicide victims by *in situ* hybridization and quantitative PCR. Our data demonstrated a different expression pattern in humans as compared to rodents. Both CRH-R1 and CRH-R2 were expressed in high amounts in the brain with the strongest expression in the pituitary. Strong expression of both CRH-R1 and CRH-R2 in human pituitaries suggests that

particularly under stress, activation of the HPA axis can be maintained through both receptors. In conclusion, both CRH-R1 and CRH-R2 are widely expressed in human tissues. The distribution differs from rodents, suggesting that results from animals cannot easily be translated to humans. Strong expression of CRH-R2 in human pituitaries and a shift in the CRH-R1/R2 ratio in pituitaries of suicide victims suggest that particularly under stress, activation of the human HPA axis can be maintained through both receptors."(Hiroi et al., Molecular Psychiatry, 2001, Vol. 6, pages 540-546).

"Crticotropin-releasing hormone (CRH) interacts with noradrenergic, dopaminergic and cholinergic systems of the brain, and these interactions are thought to be of relevance for the stress response, anxiety-related behavior, and cognitive function. The results clearly demonstrate that the cholinergic and catecholaminergic systems provide direct anatomical substrates for CRH action through the CRH-R1. these findings are of particular relevance for understanding the action of recently developed CRH-R1 antagonistic drugs which may offer a new therapeutic approach to treat stress-related disorders such as anxiety and depression and their concomitant alterations in arousal and cognitive functions." (Sauvage et al., Neuroscience, Vol. 104, pages 643-652).

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is

necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claim 1 would be useful for treating a pharmacological condition in a subject.

Amount of guidance/working examples: The preparation of example compounds has been described on pages 231-233. The ability of the example compounds to have inhibitory effects on CRF-induced is shown in the specification (pages 234-244). However, applicant has not guidance or examples for treating depression, anxiety, mania, panic disorder, phobia, obsessive-compulsive disorder, posttraumatic stress disorder, affective disorder, dysthymia, bipolar disorder, cyclothymic personality or schizophrenia.

The breadth of the claims: The breadth of claims is drawn to a therapeutic method for a disease associated with cortocotropin releasing factor (CRF) or depression, anxiety, mania, panic disorder, phobia, obsessive-compulsive disorder, posttraumatic stress disorder, affective disorder, dysthymia, bipolar disorder, cyclothymic personality or schizophrenia, using a compound of formula (I).

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating a disease associated with corticotrophin releasing factor (CRF), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 20-22, for treating a disease associated with corticotrophin releasing factor (CRF), have been enabled by the instant specification.

7. Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating specific diseases, does not reasonably provide enablement for preventing diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants are not enabled for preventing any of these diseases. The only established prophylactics are vaccines not the compounds such as present here. In addition, it is presumed that "prevention" of the claimed diseases would require a method of identifying those individuals who will develop the claimed diseases before they exhibit symptoms. There is no evidence of record that would guide the skilled clinician to identify those who have the potential of becoming afflicted.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art, and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. 1) As discussed above, preventing diseases requires identifying those patients who will acquire the disease before *** occurs. This would require extensive and potentially opened ended clinical research on healthy subjects. 2) The passage spanning line 25, page 7 to line 4, page 10 lists the diseases Applicant intend to treat. 3) There is no working example of such a preventive procedure in man or animal in the specification. 4) The claims rejected are drawn to medical treatment, and are therefore physiological in nature. 5) The state of the art is that no general procedure is art-recognized for determining which patients generally will become afflicted with diseases before the fact. 6) The artisan using Applicants invention would be a Board Certified physician who specialized to treat diseases with an MD degree and several years of experience. Despite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for the prevention of disorder diseases generally. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been

presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006. This establishes that it is not reasonable to any agent to be able to prevent disorders generally. That is, the skill is so low that no compound effective generally against disorders has ever been found let alone one that can prevent such conditions. 7) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). 8) The claims broadly read on all patients, not just those undergoing therapy for the claimed diseases and on the multitude of compounds embraced by Formula (I).

The Examiner suggests deletion of the word "prevention".

8. *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

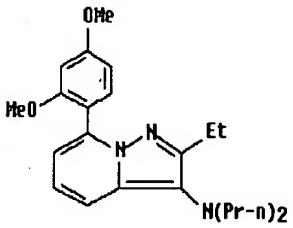
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology

Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Fu et al., US 7,151,109. Fu et al. disclosed the instant claims compound which is from STN search

RN 475171-39-2
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,4-dimethoxyphenyl)-2-ethyl-N,N-dipropyl



.Therefore, the instant claims are anticipated by Fu et al.

9. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Hibi et al., US 7,091,215. Hibi et al. disclosed the instant claims compound which is from STN search

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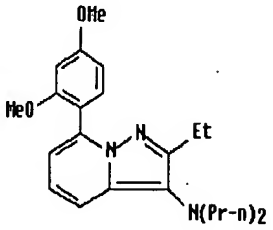
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N,N-dipropyl-



RN 475171-39-2
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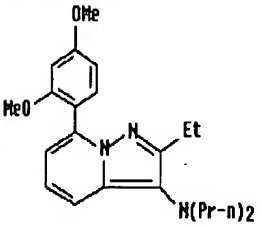
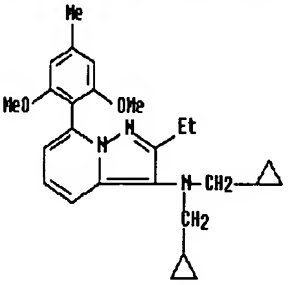
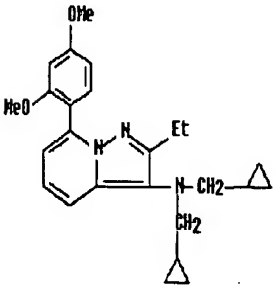


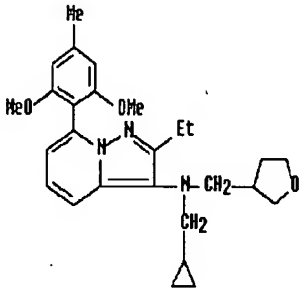
RN 475171-46-1
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl



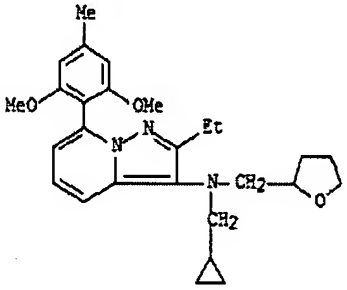
RN 475171-49-4
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,4-dimethoxyphenyl)-2-ethyl



RN 475171-71-2
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-[(tetrahydro-3-furanyl)methyl]



RN 475171-72-3
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-[(tetrahydro-2-furanyl)methyl]



RN 475171-74-5
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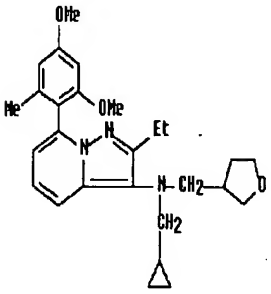
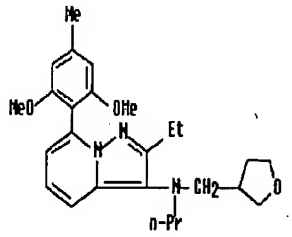
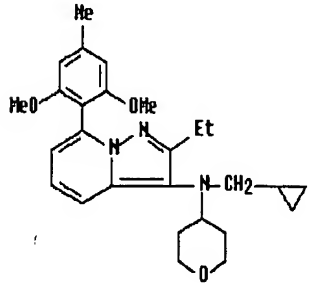


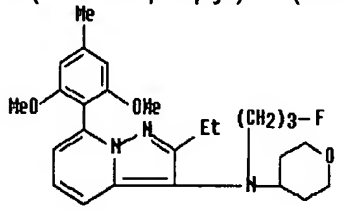
RN 475171-80-3
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-propyl-N-[(tetrahydro-3-furanyl)methyl]



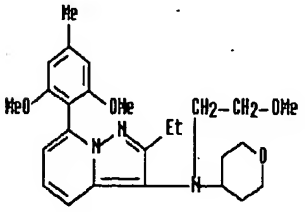
RN 475171-91-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-(tetrahydro-2H-pyran-4-yl)



RN 475171-92-7
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-(3-fluoropropyl)-N-(tetrahydro-2H-pyran-4-yl)



RN 475171-93-8
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-(2-methoxyethyl)-N-(tetrahydro-2H-pyran-4-yl)



RN 475171-94-9
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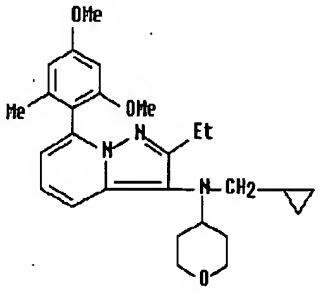
methylphenyl)-2-ethyl-N-(tetrahydro-2H-pyran-4-yl)



RN 475171-96-1
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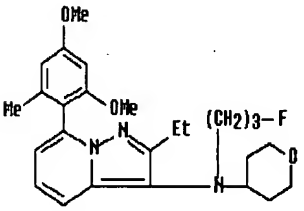
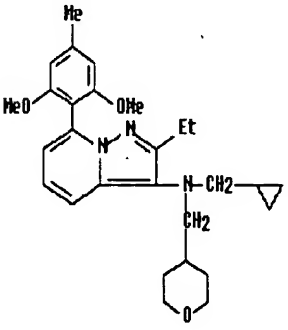


RN 475171-97-2
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-2-ethyl-7-(2-methoxy-4,6-dimethylphenyl)-N-(tetrahydro-2H-pyran-3-yl)



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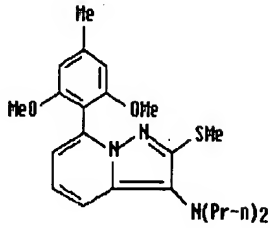

RN 475172-12-4
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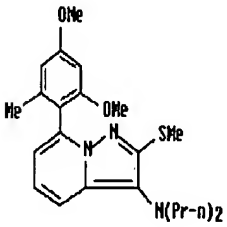
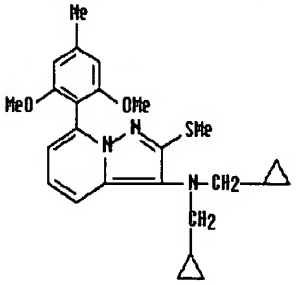
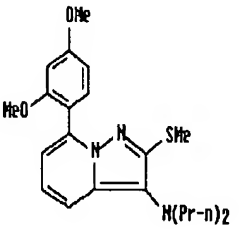


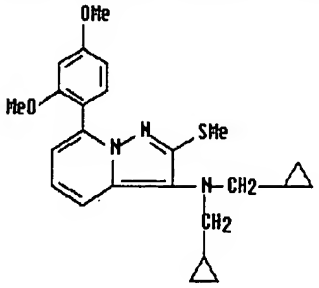
RN 475172-14-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)



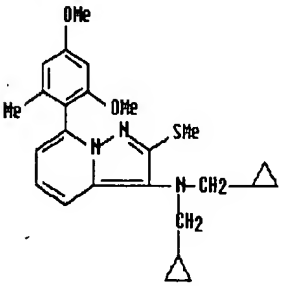
RN 475172-24-8
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,4-dimethoxyphenyl)-2-(methylthio)-N,N-dipropyl



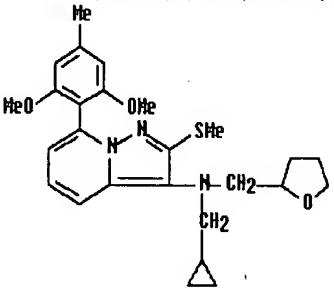
RN 475172-25-9
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,4-dimethoxyphenyl)-2-(methylthio)



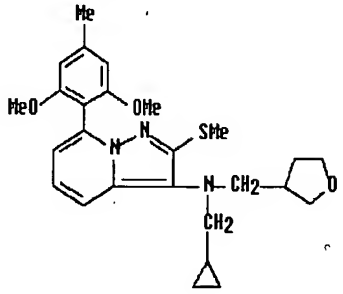
RN 475172-31-7
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-(methylthio)



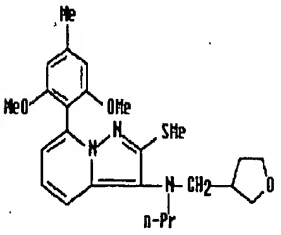
RN 475172-62-4
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-[(tetrahydro-2-furanyl)methyl]



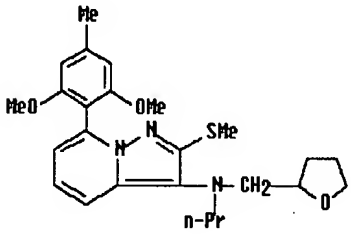
RN 475172-65-7
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-[(tetrahydro-3-furanyl)methyl]



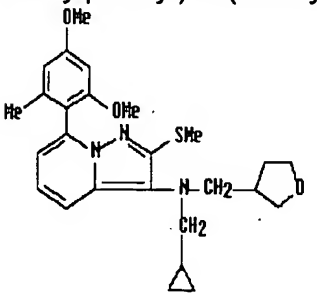
RN 475172-67-9
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-propyl-N-[(tetrahydro-3-furanyl)methyl]



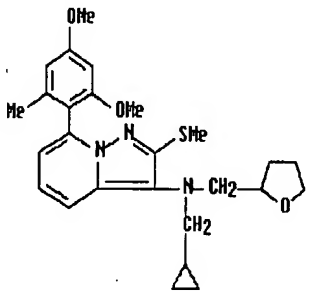
RN 475172-76-0
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2-methoxy-4,6-dimethylphenyl)-2-(methylthio)-N-propyl-N-[(tetrahydro-3-furanyl)methyl]



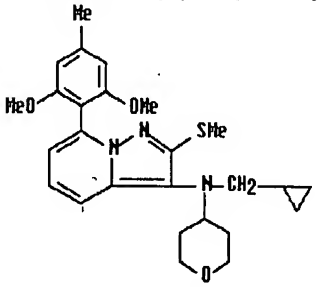
RN 475172-80-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-(methylthio)-N-[(tetrahydro-3-furanyl)methyl]



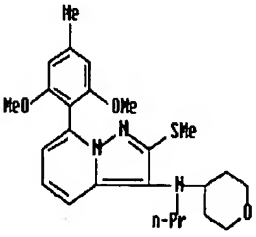
RN 475172-81-7
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,4-dimethoxy-6-methylphenyl)-2-(methylthio)-N-propyl-N-[(tetrahydro-3-furanyl)methyl]



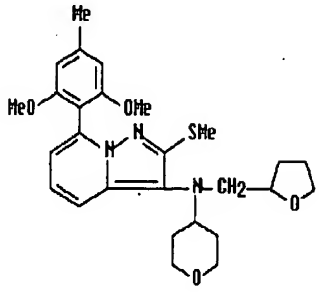
RN 475173-04-7
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-(tetrahydro-2H-pyran-4-yl)



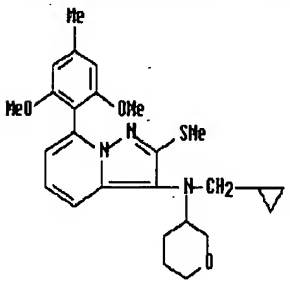
RN 475173-05-8
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-propyl-N-(tetrahydro-2H-pyran-4-yl)



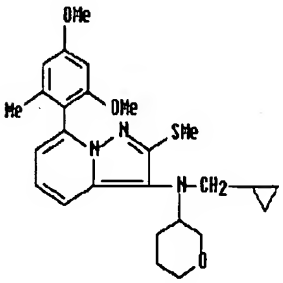
RN 475173-21-8
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-[(tetrahydro-2-furanyl)methyl]-N-(tetrahydro-2H-pyran-4-yl)



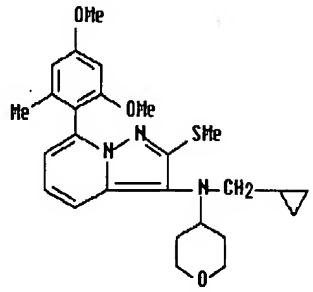
RN 475173-24-1
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-(tetrahydro-2H-pyran-3-yl)



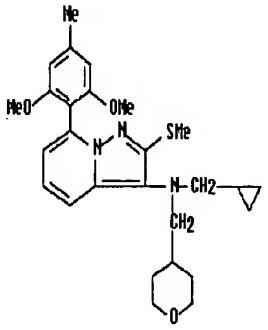
RN 475173-25-2
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-(methylthio)-N-(tetrahydro-2H-pyran-3-yl)



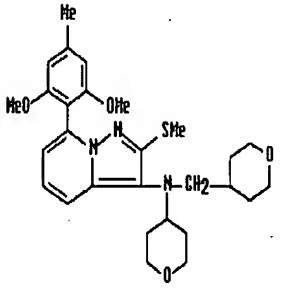
RN 475173-26-3
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-(methylthio)-N-(tetrahydro-2H-pyran-4-yl)



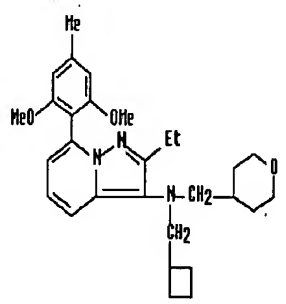
RN 475173-28-5
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-[(tetrahydro-2H-pyran-4-yl)methyl]



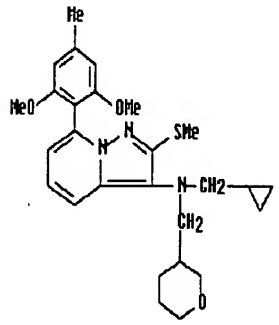
RN 475173-32-1
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-(tetrahydro-2H-pyran-4-yl)-N-[(tetrahydro-2H-pyran-4-yl)methyl]



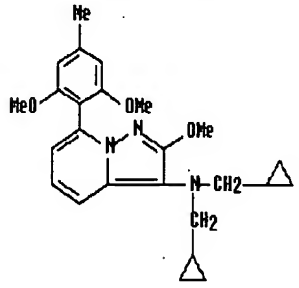
RN 475173-37-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclobutylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-[(tetrahydro-2H-pyran-4-yl)methyl]



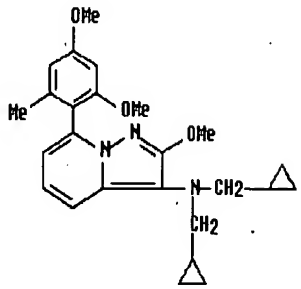
RN 475173-40-1
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N-[(tetrahydro-2H-pyran-3-yl)methyl]



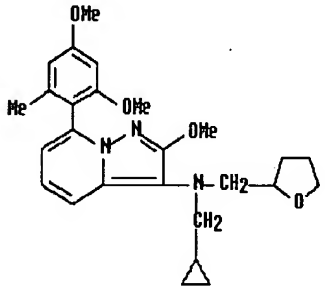
RN 475173-81-0
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy



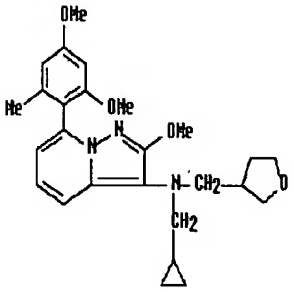
RN 475173-82-1
CN Pyrazolo[1,5-a]pyridin-3-amine, N,N-bis(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-methoxy



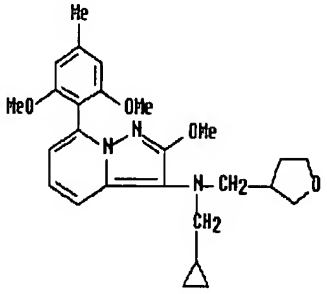
RN 475173-87-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-methoxy-N-[(tetrahydro-2-furanyl)methyl]



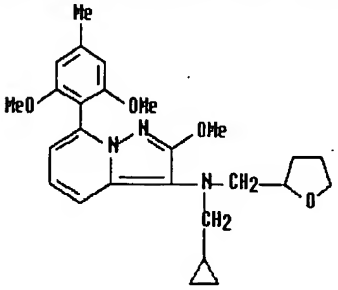
RN 475173-92-3
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-methoxy-N-[(tetrahydro-3-furanyl)methyl]



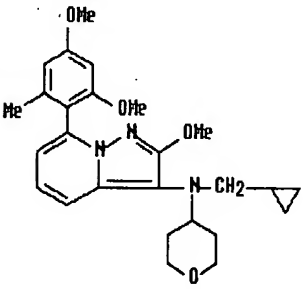
RN 475173-93-4
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-[(tetrahydro-3-furanyl)methyl]



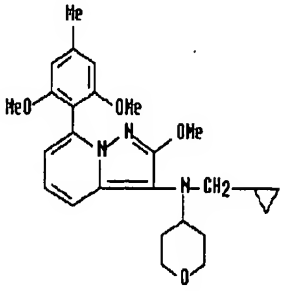
RN 475173-94-5
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-[(tetrahydro-2-furanyl)methyl]



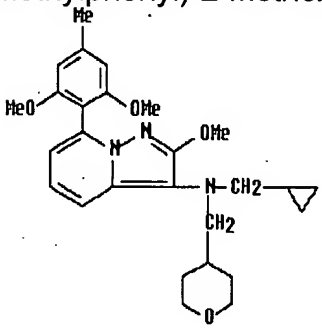
RN 475174-07-3
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-methoxy-N-(tetrahydro-2H-pyran-4-yl)



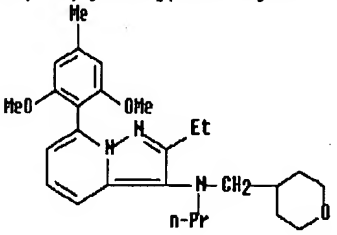
RN 475174-08-4
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-(tetrahydro-2H-pyran-4-yl)



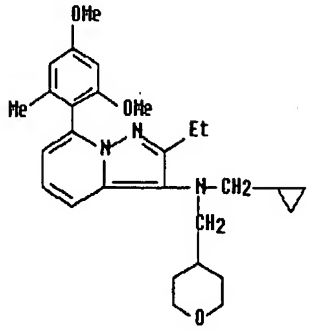
RN 475174-10-8
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-[(tetrahydro-2H-pyran-4-yl)methyl]



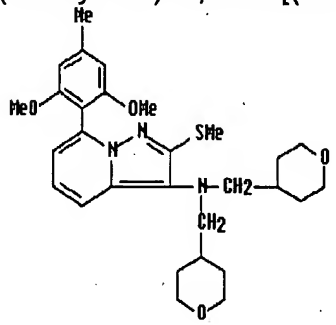
RN 475174-26-6
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-ethyl-N-propyl-N-[(tetrahydro-2H-pyran-4-yl)methyl]



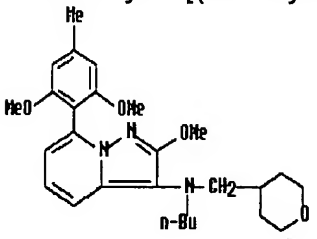
RN 475174-34-6
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-ethyl-N-[(tetrahydro-2H-pyran-4-yl)methyl]



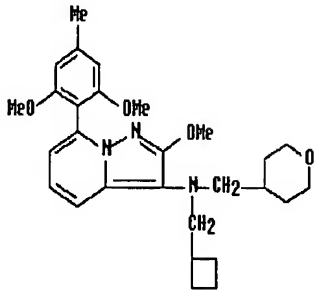
RN 475174-43-7
CN Pyrazolo[1,5-a]pyridin-3-amine, 7-(2,6-dimethoxy-4-methylphenyl)-2-(methylthio)-N,N-bis[(tetrahydro-2H-pyran-4-yl)methyl]



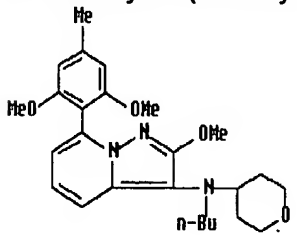
RN 475174-48-2
CN Pyrazolo[1,5-a]pyridin-3-amine, N-butyl-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-[(tetrahydro-2H-pyran-4-yl)methyl]



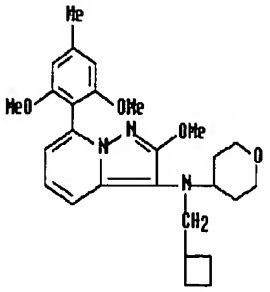
RN 475174-49-3
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclobutylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-[(tetrahydro-2H-pyran-4-yl)methyl]



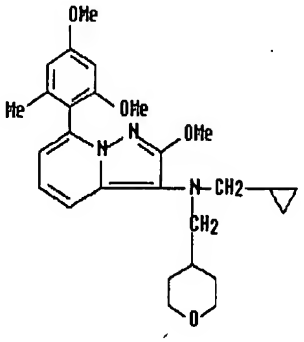
RN 475174-51-7
CN Pyrazolo[1,5-a]pyridin-3-amine, N-butyl-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-(tetrahydro-2H-pyran-4-yl)



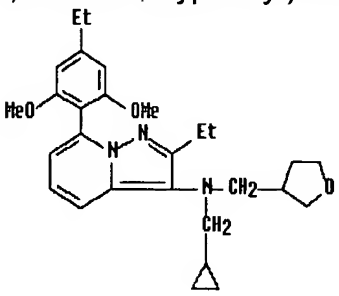
RN 475174-52-8
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclobutylmethyl)-7-(2,6-dimethoxy-4-methylphenyl)-2-methoxy-N-(tetrahydro-2H-pyran-4-yl)



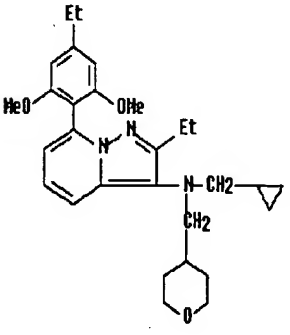
RN 475174-61-9
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-7-(2,4-dimethoxy-6-methylphenyl)-2-methoxy-N-[(tetrahydro-2H-pyran-4-yl)methyl]



RN 475174-62-0
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-2-ethyl-7-(4-ethyl-2,6-dimethoxyphenyl)-N-[(tetrahydro-3-furanyl)methyl]



RN 475174-63-1
CN Pyrazolo[1,5-a]pyridin-3-amine, N-(cyclopropylmethyl)-2-ethyl-7-(4-ethyl-2,6-dimethoxyphenyl)-N-[(tetrahydro-2H-pyran-4-yl)methyl]



.Therefore, the instant claims are anticipated by Hibi et al.

10. ***Claim Rejections - Obvious Double Patenting***

Claims 1-11 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-23 of

the US 7,091,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hibi et al. US 7,091,215 claimed compounds in claims 1-23, which have the same structural core as the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims 1-11 and the prior art claims 1-23 is that the definition of Ar in the prior art is broader than the phenyl ring of the instant application.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The instant claims 1-11 are therefore fully embraced by the prior art claims 1-23.

This is obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1,1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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01/26/2007
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